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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,916	05/09/2006	Peter MacDonald	13150/46201	6750

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EXAMINER	
BASQUILL, SEAN M	

ART UNIT	PAPER NUMBER
1612	

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04/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,916	MACDONALD ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed International Patent Application PCT/EP03/50925 under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d) related to EPO Application 02027534.3, which papers have been placed of record in the file.

Claim Objections

2. Claim 4 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 4 has not been further treated on the merits.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Claims fail to define what is meant by the dotted line between carbons 1 and 2 in the pregnane ring.

4. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 8 recites the broad limitation “an amine salt,” and the claim also recites “wherein the amine salt is preferably pyridine methylsulfonate,” which is the narrower statement of the limitation. Similarly, Claim 9 recites the broad limitation “wherein the amount of amine salt is from 0.1-100. . . percent by weight, referred to the amount of compounds of formula II,” and the Claim also recites “and preferably 50-90 percent by weight, referred to the amount of compounds of formula II” which is the narrower statement of the range.

5. Claim 8 recites the limitation "the amine salt" in Claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5-8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,794,503 (hereinafter "La Loggia").

La Loggia describes the preparation of 6a-fluoro-9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione-21-acetate by reaction of 15g 9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione with isopropyl acetate and 0.6g p-toluenesulfonic acid to form the di-acetate, the reaction which was then quenched with 0.48ml triethylamine and acetonitrile. (C.5, L.35-50). Additional acetonitrile was added after evaporation of the previous solution, along with ACCUFLUOR, e.g., 1-Fluoro-4-hydroxy-1,4-diazoniabicyclo [2.2.2]octanebis(tetrafluoroborate), and the reaction was permitted to continue at 0C for 12 hours. Solid 6a-fluoro-9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione-21-acetate was obtained as a solid which was then cleaned by water and ammonia rinse to yield 6a-fluoro-9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione-21-acetate in a 6a:6B configuration ratio of 93.5:6.5. (C. 5, L.50-60). From the amounts of chemicals used in the reaction as given, the examiner has concluded, assuming all reactions were perfectly

efficient, the reaction would yield 18.24g of 9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione diacetate and 0.95g triethylamine-p-toluenesulfonate, for a reaction which uses 5.2% of the amine salt referred to the amount of compounds of Formula II.

7. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,255,331 (hereinafter MacDonald").

MacDonald describes 3,21-diacetoxy-9B,11B-epoxy-16a-methyl-pregna-3,5-diene-20-one. (C.1, L.62-63).

8. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(e) as being anticipated by International Patent Application Publication WO03/047329 (hereinafter "Chernyak").

Chernyak describes processes for the formation of compounds of Formula I as described in the instant application by reacting a solution containing 5g of 17hydroxy-9B,11B-epoxy-16—methyl-pregna-1,4-diene-3,20-dione 21 acetate with 50ml isopropylidene acetate and 0.25ml concentrated sulfuric acid to form the 3-acetate enol ester. (Pg.14, L.14-16). The excess sulfuric acid was then neutralized by addition of triethylamine, and the remaining solvent removed to provide the 3-enol acetate ester and a salt of a strong acid and nitrogenous base. (Pg.14, L.16 - Pg. 15, L.1). This residue was then dissolved in acetonitrile and F-TEDA (generic name for SELECTFLUOR) was added. (Pg.15, L.1-3). From the amounts of chemicals used in the reaction as given, the examiner has concluded, assuming all reactions were perfectly efficient, the reaction would yield 5.50 grams of the enol ester and 0.91g of the sulfuric acid/triethylamine salt, yielding a reaction using 16% of the amine salt referred to the amount of compounds of

Formula II. The examiner points out that Chernyak does not add water to the solution until after the reaction had completed, similar to the methods described in the instant application Examples A1-A6 and B1-B6.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 10 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. 4,255,331. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the prior art patent anticipate the instant claim.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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